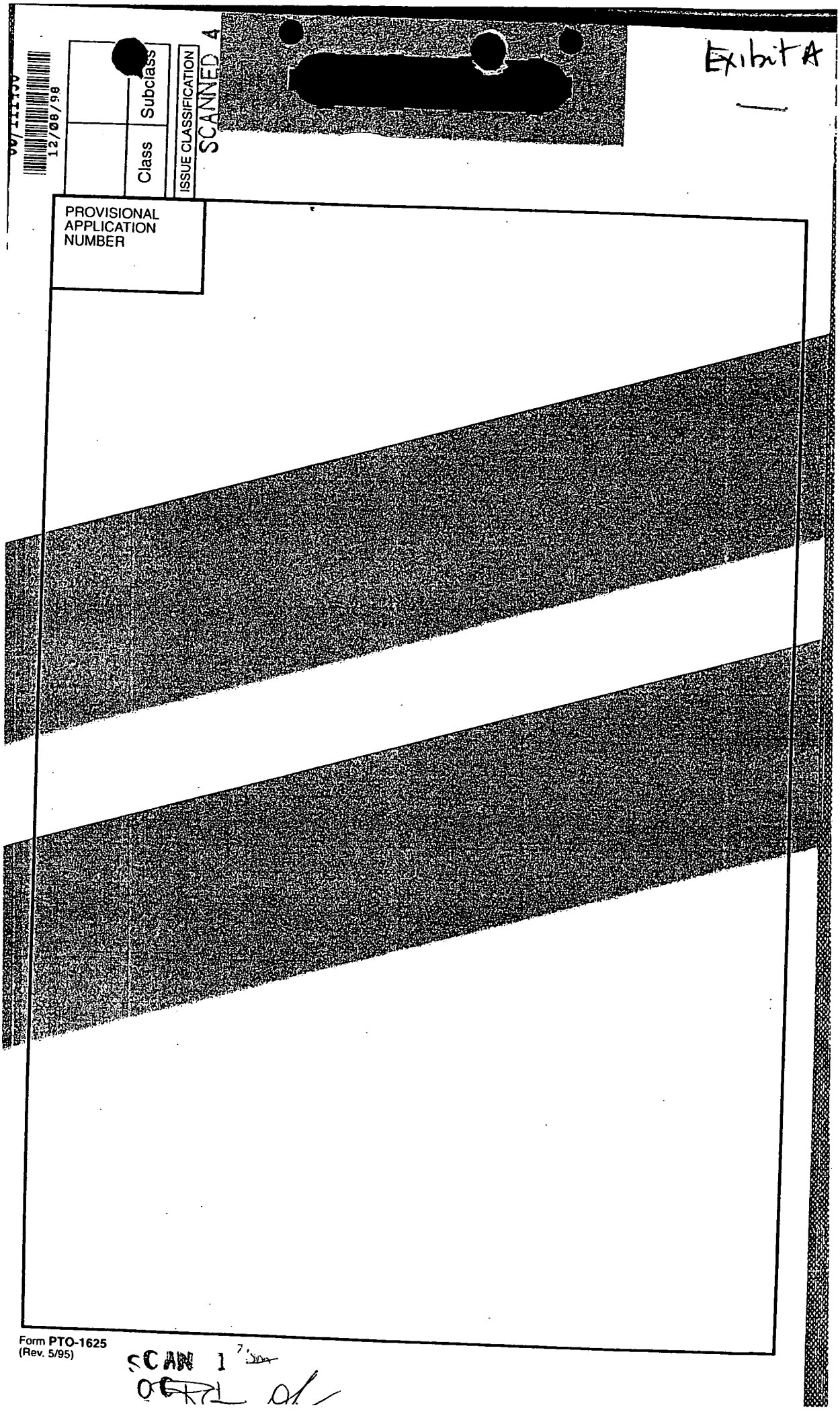
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APPLICANT

JOSEPH NEEV, LAGUNA BEACH, CA.

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TITLE

METHOD AND APPARATUS FOR SURGERY AND MATERIAL PROCESSING

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PROVISIONAL APPLICATION COVER SHEET [37 CFR 1.53(c)]

This is a request for filing a PROVISIONAL APPLICATION under 35 U.S.C. §111(b) and 37 CFR 1.51(a)(2)

Date : December 8, 1998

Docket No. : 33826/NEC/Y54

INVENTOR(S)/APPLICANT(S) (LAST NAME, FIRST NAME, MIDDLE INITIAL, RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)

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____ Additional inventors are being named on separately numbered sheets attached hereto.

TITLE OF THE INVENTION (280 characters max)

A METHOD AND APPARATUS FOR SURGERY AND MATERIAL PROCESSING

ENCLOSED APPLICATION PARTS

__32__ Specification (number of pages)

__10__ Drawings (number of sheets)

__X__ Small Entity Statement

____ Assignment

____ Other (specify):

FEE AND METHOD OF PAYMENT

__X__ A check for the filing fee of $__75.00__ is enclosed.
The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required by this filing to Deposit Account No. 03-1728. Please show our docket number with any charge or credit to our Deposit Account. **A copy of this letter is enclosed.**

____ No filing fee enclosed.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

__x__ No ____ Yes, the name of the U.S. Government agency and the Government contract number are:

Please address all correspondence to **CHRISTIE, PARKER & HALE, LLP, P.O. Box 7068, Pasadena, CA 91109-7068, U.S.A.**

(Mail to BOX PROVISIONAL PATENT APPLICATION)

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

This paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10, Mailing Label No. EL125822305US.

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A METHOD AND APPARATUS FOR SURGERY AND MATERIAL PROCESSING

LIST OF ILLUSTRATIONS:

Figure 1A: An exemplary Continuous Wave system with scanner for material removal and modification.

Figure 1B: An exemplary Continuous Wave system with scanner for material removal and modification showing a typical delivery system, the scanner and various guidance tips.

Figure 1C: An exemplary system of a suspended laser-gun and scanner.

Figure 1D: Hand held or tripod mounted laser-gun and scanner alternative design showing the various tissue effect tip.

Figure 2A: Scanning pattern for the material ablator/ modifier.

Figure 2B: Scanned ablation pattern and coolant spraying.

Figure 3: Method and apparatus for hair removal

Figure 4A: The effect of active cooling as a function of time.

Figure 4B: The effect of active cooling as a function of depth.

Figure 5: A treatment cup for reduction of pain and control of ambient tissue conditions.

Disclosed is a method and apparatus for material processing and tissue removal which substantially reduces the amount of pain (in medical applications) and the amount of residual heat in the tissue or material.

METHOD AND APPARATUS, SYSTEM 1:
UTILIZING CW LASERS

The principles of operation for an exemplary material removal and modification system are described in detail in the following sections. The system (see various embodiments in Figure 1) comprises a source of continuous wave (CW) electromagnetic radiation which complies with the requirements of the invention,

as discussed below. In the following discussion, a laser source is used as an exemplary pulsed source of electromagnetic radiation. However, those skilled in the art, will recognize that the invention is not limited to laser sources and other sources of CW electromagnetic radiation may serve equally well in the practice of the invention.

The principles of operation of such an exemplary laser system will now be developed in connection with the mechanisms for material and tissue processing. For example, the machining of silicon surfaces, removal of skin tissue or the treatment and removal of dental hard and soft tissue and materials may be accomplished according to the present invention.

The description of the operation of this laser system with respect to applications of silicon machining or dental tissue processing is used for exemplary purposes only and is not intended to limit the applications of the present invention, not to limit the scope of the claims.

As will be described in greater detail below, the apparatus and methods for this invention have application for a wide variety of material modification, removal and processing. Additionally, the laser system of the present invention has exceptional utility for biomedical, surgical and micro-machining purposes.

The inventor has identified an electromagnetic source and material operational parameter regime which provides interaction characteristics that are superior to conventional machining, laser machining, established material processing and material modification systems.

Advantageously, the aspect of the present invention relating to the method's reliance on the system's ability to limit the amount of energy coupled to the material, and the system's ability to remove most of the residual deposited energy generated by the interaction itself, results in a very significant reduction in the level of collateral damage and pain.

WHAT IS CLAIMED:

1. A method for material removal and/or modification, the method comprising the steps of:

directing a beam of a continuous wave energy at the material so as to ablate a quantity of the material and/or so as to permanently modify a quantity of the material, the beam being configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby;

means for focusing the source's output beam to a small spot size, in the range of from about 1μm to about 1mm and preferably in the range of from about 5 μm to about 200 μm;

the continuous wave energy source having an average power of from about 0.001 W to about 10 kW, and preferably from about 1W to about 1KW;

means for generation rapid beam movement;

means for generating a predetermined pattern of beam movement; and

using the means for generating the rapid beam movements to limit the dwell time (the time it takes the beam to move over a single point in space) to from about 1 ps to about 100 ms and preferably from about 1μs to about 1ms.

2. The method of claim 1 further comprising:

moving the beam after a line segment is ablated or modified to ablate or modified a line segment substantially removed from said first line to be modified so that heat deposited in said first line is not sufficient to raise the temperature of the tissue in the vicinity of said second line above the threshold for irreversible modification of the tissue, and, in biotissue, above the threshold for pain; and

returning the beam after it has completed ablating or modifying the second line to the vicinity of the first line and ablating or modifying a third line, such ablation or modifying sequence is further continued as the beam is moved in alternating fashion between sequential lines below line 1 and line 2 until the entire pre-selected area is completely ablated or modified in a continuous and uniform manner.

3. The method of claim 1 further comprising means for cooling the ablated surface, said means for cooling the ablated surface is applied after a line segment was ablated and before an adjacent line is ablated.

4. The method of claim 2 further comprising means for cooling the ablated surface, said means for cooling the ablated surface is applied after a line segment was ablated and before an adjacent line is ablated.

5. The method of claim 1 further comprising applying a coolant, which does not block or interfere with laser action, said coolant is applied after irradiation is completed

6. The method of claim 1 further comprising applying a coolant prior to the irradiation step, while said coolant does not block or interfere with beam-target interaction. Coolant will reduce the temperature of the entire region, e.g, in ~ 40 ms the coolant will reduce the temperature of about 200 μm depth of tissue. As long as the coolant does not interfere with the incoming beam (for example the applied coolant material has evaporated by the time the laser beam is applied), the incoming beam will create an intense heat (created by the subsequent beam-tissue interaction) that will only effect a volume about 10-30 μm deep. A high absorption by the source's wavelength (and/or a desired

intense interaction) will easily overcome the extra heat needed at the surface, yet the residual heat left subsequent to the interaction and at the time the beam is turned off or moved away, will be mitigated by the coolant lowering of temperature to a depth of about 200 μm. Minimization of thermal damage and pain will thus be effected. Figure 4A and Figure 4B illustrate the principle of operation of active cooling.

Figure 4A shows the effect of active cooling after application of the laser beam to the target. Here, in the upper frame, the curve 410 illustrates the surface temperature response of the tissue to the laser alone. The lower frame shows also the response 420 of the tissue when the heating of the laser is quenched by the application of active cooling. It is clear that the application of coolant rapidly removes excess heat and reduces temperature at the targeted tissue. Figure 4B illustrates the expected coolant-laser temperature profiles as a function of depth into the tissue. The effect of laser action alone is shown by curve 450 and as expected causes a raise in temperature. Heat diffusion brings the deeper layers temperature up with time and it is clear that the nerve endings 460 are well within the heated region when the laser acts alone. The effect of cooling with time is to lower the temperature of deeper lying regions. Nerve endings lying underneath the skin epidermis are shown by the small boxes 460. The effect of the application of active cooling with the laser is shown in the lower frame by curve 480. The cooling action applied before the laser is not sufficient to lower the very high temperature of the actual interaction volume (usually equal to spot size and on the order of about tens micrometers in depth) where the beam is very intense and results in ablation. However, the temperature in deeper region, heated mainly by diffusion, are much lower temperatures as can be seen in comparing curve 480 (the combined effect) to curve 450 (laser alone). As a result, the heating of

the nerve ending 460 and their temperature is much reduced and less pain is felt.

7. The method of claim 1 further comprising of the step of repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

8. The method of claim 2 further comprising of the step of repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

9. The method of claim 3 further comprising of the step of repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

10. A method for tissue processing, removal and modification while minimizing pain, the method comprising the steps of:

directing a beam of a continuous wave energy at the biological tissue so as to ablate a quantity of the material and/or to permanently modify a quantity of the material, the beam being configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby, and minimizes pain; and

creating an ambient environment surrounding said ablated or modified tissue which minimizes chemical or physical stimulation to the ablated or modified target tissue. Creating an ambient environment surrounding said ablated or modified tissue may involve a type of suction/treatment cup (Figure 5) with a suitable window at the top, said window allows transmission of

selected beam radiation (for example, a 10.6 μm radiation will require an exemplary ZeSe window, while visible radiation can use fused silica). Said suction cup may further include a heating element and heat sensor to maintain inside temperature roughly that of the body, and smoke evacuation to allow removal of unwanted debris.

11. The method as recited in claim 10, wherein the stimulation causes pain.

12. A method for scanning a substantially continuous beam of electromagnetic radiation upon a surface, the method comprising the steps of moving the beam within a predetermined area upon the surface, the beam being moved such that heat density from the beam upon the surface is mitigated.

13. The method as recited in claim 12, wherein the beam is moved within the predetermined area in a manner which maintains heat density of the surface, unablated tissue, below a predetermined threshold value.

14. The method as recited in claim 12, wherein the beam is moved within the predetermined area in a manner which maintains heat density at the unablated tissue surface below a value which results in pain.

15. The method as recited in claim 12, wherein the beam is moved within the predetermined area in a manner which maintains heat density at the unablated material below a value which results in material modification.

16. The method as recited in claim 12, wherein the beam is moved so as to cover substantially the extra predetermined area.

17. The method as recited in claim 12, wherein a path of the beam upon the surface of the predetermined area comprises a plurality of discontinuities, the discontinuities facilitating movement of a new portion of the beam path away from an old portion of the path, so as to mitigate heating of the surface proximate the old path as the beam defines the new path.

18. The method as recited in claim 12, wherein sufficient time is provided to allow previously scanned spot to cool to below a predetermined temperature before scanned occurs sufficiently close to the previously heated spot to cause the temperature of the previously scanned spot to decrease.

In Summary:

First Note:

Claim 10 is important because it addresses the issue of pain, which is generated outside the actual interaction of and electromagnetic source or laser with the target tissue. Pain is generally generated from mechanical, chemical, or other physical stimulation of nerve ending. Thus when a region of animal tissue which contain nerve ending is exposed to for example pressure, air flow, heat, chemical reaction or any other type of physical and or chemical stimulation, pain is felt. Our method both minimizes the stimulation due to the actual action of the laser or electromagnetic source beam, and, as claim 10 above state, also address the issue of pain generated in the exposed tissue. By creating an ambient environment (before, during or after beam action) which prevent temperature changes (and thus also, the associated mechanical changes) air flow, and in general any possible mechanical physical or chemical stimulation, much of the pain can be eliminated.

A continuous wave electromagnetic source is preferably used. The source preferably emits radiation with power of 1mw to 1 KW and in particular power lever of 1 W to 100 W. The beam is focused to a spot size at the target ranging from about 5 μm to about 5mm and in particular form about 10μm to about 300 μm. The Continuous Wave electromagnetic beam is then rapidly moved from one location to the next so that the dwell time at each site (i.e. the time it takes the beam to sweep an area of a size equal to that of the beam spot size) is between 1 ns and 100 ms and in particular between 1 μs and 1ms.

It is also preferable in the practice of the invention that the means for moving the beam from one location to the next is capable of moving the beam focused spot along a horizontal line and then down to an area sufficiently removed from the first line location so that when the total amount of energy deposited in the line is thermally conducted throughout the entire volume within the reach of thermal diffusion and prior to the return of the beam to the first location - result in temperature increase substantially below that of irreversible thermal damage or that of the sensation of pain.

For an exemplary 100 μm spot size and a line 1 cm long scanned in an exemplary time of about 10 ms, (a dwell time of 10ms/100 spots = 100 μs = tdwell) and with a CW source of an exemplary 10 W and an exemplary absorption depth of about 10μm, would deposit 0.1 Joule spread over about 1cm long X 300 μm wide X 110μm deep rectangular approximate volume. (This if we assume that we return to the vicinity of the original line within about 30 ms of the end of the original line).

For practical reasons the target may simply be an area divided into two sections where we alternate between ablating the upper

portion and ablating the lower portion so that in practice the separation is much larger than that required by the simple approximation provided above. See figure 2A.

Further, to enhance the removal of thermal energy, a cooling agent may be applied after the source's energy had been applied and the ablative interaction phase has been completed. Figure 2B illustrates the following discussion. If cooling is applied before or during the application of source's energy, ablative material removal and/or modification may be compromised due to direct interference with the beam or prevention of the beam from arrival at the targeted material surface, or the interaction may be compromised due to cooling and modifying of material PRIOR to the material interaction.

The coolant may be a fluid (liquid or gas) or even gel or solid (e.g. powder) or even utilizing the well-known Thermo-electric effect (or Peltier cooler). What ever the cooling media or procedure is, the coolant must both be effective in the removal of the previous line heat, and be removed off the surface to the extent that it no longer inhibit the interaction of the next interacting line (i.e. the substance which produce the cooling of the surface and the additional removal of heat) must substantially evaporate or otherwise removed prior to the 30 ms interval prior to the arrival of the beam for the next line.

In Figure 2A, a first ablation line 10 is made in the upper portion A of the target above line 70. For example, for a total sample size of 1cm X 1cm, line 70 dividing the upper portion A and the lower portion B would be 0.5 cm down the sample. Line 10 is made, as discussed above within approximately 10 ms exemplary on an exemplary time scale, the beam is then turned off (or the surface is shielded) for the 10 ms (or less) travel duration of

line 20, the beam is then on for time of 10 ms ablating the line 30, and then the beam is turned off again for the time it takes to move along line 40 to start a new line 50 close to the first line 10. The process then repeated until the entire area (A + B of Figure 2A) has been ablated or modified.

The coolant can be applied to the upper segment A of Figure 2A (e.g. the vicinity of line 10) while the beam (either active or not) is moved along line 20, 30 and 40. By the time the beam is ready to interact and remove/modify line 50, adjacent to line 10, substantially much of the coolant should be removed from the vicinity of line 10 and 50.

The process of ablating subsequent alternating lines in zone A and B is then repeated with, for example, lines 80, adjacent to line 50, in region A being ablated followed by line 90, adjacent to line 60, in region B followed by line 100 in region A followed by line 110 in region B and so on until the entire targeted area A and B are ablated or modified.

Total interaction time for a 1cm X 1cm area using a sequential continuous scan, is given by the following:

a 1cm long area composed of a continuum of adjacent 0.01 cm thick lines contains 1.0 cm/0.01cm thick 100 lines.

with a spot size of 100 μm and a dwell time of 100 μs, each 1cm line will require 10 ms. Thus the total scan time of an area 1cm X 1cm is:

100 lines X 10ms /line = 1 second

The total interaction time to complete a single pass over an alternating upper/lower area of 1cm X 1cm is:

100 X 20 ms = 2 seconds

Thus the scanning time is doubled due to the switching back and forth, in comparison to a sequential scanning, (i.e. going from line 10 in figure 2A directly to adjacent line 50 then to line 80 then to line 100 etc.).

At 40 ms after start (the time it takes for the beam to go through the round trip starting at point 210 (See figure 2B) and ending at point 220, the heat is deposited at an exemplary point 210 has diffused about 200 μm away from that point. The deposited thermal energy is thus spread over an area which is approximately 10 times larger then the original area of 100 µm beam energy deposition (500 µm / 100 µm)^2 = 25.

The ratio of the new to the original volume which the deposited thermal energy is now occupying may even be larger. For example, for 10.6 µm radiation, the original heat deposition is only about 20 µm. By the time the beam is back at near the starting point, (at point 220 in Figure 2B) the heat has diffused additional 200 µm down. Thus the new volume is approximately 25 X 10 = 250 times larger than the original volume.

The present invention also discloses active cooling of the irradiated target: As the beam is moved away from an exemplary line 10 in the upper section A, and prior to its arrival at the vicinity of point 220 of Figure 2A, a coolant fluid (which can be liquid, solid or gas) is applied to the previously irradiated area around line 10. This is illustrated in Figure 2B. The active cooling allow faster, most efficient removal of heat and thus minimizes thermal damage and minimizes pain. The effect of the applied coolant, however, must not detract or negatively effect the effectiveness of the tissue-beam interaction.

The net result is a an interaction dominated by efficient three dimensional diffusion with Heat removal cooling done after the irradiation to further enhance removal of heat and minimization of pain. Figure 5 illustrates such a suction/treatment cup.

DEVICE

WHAT IS CLAIMED IS:

1. A device for ablating or modifying a material, the device comprising:

a source of continuous wave energy said continuous wave energy source having an average power of form about 0.001W to about 10 kW and preferably from about 1W to about 1 KW;

delivery components such as an articulated arms, hollow wave guide optical fiber, a set of mirrors, lenses and other optical and electro-optical components, or other means for delivering the beam from said source of continuous wave energy to a device for changing output beam characteristics;

an apparatus for changing beam characteristics consisting of an element to focus the source's output beam to a very small spot size (for example in the range of from about 1μm to about 1mm and preferably in the range of from about 1 μm to about 200 μm);

said apparatus for changing beam characteristics further consists of motorized mirrors or other motion-control mounted optical elements, diffraction gratings, acousto-optic modulators, electro-optic modulators and other similar devices for generation of rapid beam movement;

said means for changing beam characteristics further consists of means such as a function generator or a programmable microprocessor for generating a predetermined pattern of beam movement; and

using the apparatus for generating the rapid beam movement to limit the dwell time (the time it takes the beam to over a single point in space to from about 1 Ps to about 100 ms and preferably from about 1μs to about 1ms.

2. The device of claim 1 further comprising:

means such as motor-mounted mirrors, diffraction gratings, acousto-optical modulators or electro-optical modulators for moving the beam after a line segment is ablated or modified to ablate or modified a line segment substantially removed from said first line to be modified so that heat deposited in said first line is not sufficient to raise the temperature of the tissue in the vicinity of said second line above the threshold for irreversible modification of the tissue, and, in biotissue, above the threshold for pain; and

means such as electronic signal to motor mounted mirrors for returning the beam after it has completed ablating or modifying the second line to the vicinity of the first line and ablating or modifying a third line, such ablation or modifying sequence is further continued as the beam is moved in alternating fashion between sequential lines below line 1 and line 2 until the entire pre-selected area is completely ablated or modified in a continuous and uniform manner.

3. The device of claim 1 further comprising means for cooling the ablated surface, said means for cooling the ablated surface is applied after a line segment was ablated and before an adjacent line is ablated.

4. The device of claim 2 further comprising means for cooling the ablated surface, said means for cooling the ablated surface is applied after a line segment was ablated and before an adjacent line is ablated.

5. The device of claim 1 further comprising applying a coolant, which does not block or interfere with laser action said coolant is applied after irradiation is completed.

6. The device of claim 1 further comprising applying a coolant Prior to the irradiation step, while said coolant does not block or interfere with beam-target interaction.

7. The device of claim 1 further comprising means for repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

8. The device of claim 2 further comprising means for repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

9. The device of claim 3 further comprising means for repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

10. A device for tissue processing, removal and modification while minimizing pain, the device comprising the steps of:

means for directing a beam of a continuous wave energy at the biological tissue so as to ablate a quantity of the material and/or to permanently modify a quantity of the material, the beam being configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby, and minimizes pain; and

means for creating an ambient environment surrounding said ablated or modified tissue which minimizes chemical or physical stimulation to the ablated or modified target tissue such means comprising of a "treatment cup" as in Figure 5 which prevents air flow and maintains inside ambient temperature at about 37 °C, said "treatment cup" is attached to the source's output beam modifier or scanner, said attachment includes a window (for example, a zinc selunide window) allowing beam energy to pass through but not air flow.

First Note:

Claim 5 is important because it addresses the issue of pain, which is generated outside the actual interaction of and electromagnetic source or laser with the target tissue. Pain is generally generated form mechanical, chemical, or other physical stimulation of nerve ending. Thus when a region of animal tissue which contain nerve ending is exposed to for example pressure, air flow, heat, chemical reaction or any other type of physical and or chemical stimulation, pain is felt. Our device both minimizes the stimulation due to the actual action of the laser or electromagnetic source beam, and, as claim 5 above states, also address the issue of pain generated in the exposed tissue. By creating an ambient environment (before, during or after beam action) which prevent temperature changes (and thus also, the associated mechanical changes) air flow, and in general any possible mechanical physical or chemical stimulation, much of the pain can be eliminated.

Exemplary commercially available coolants are:

$C_2H_2F_4$ cryogen spray (1,1,1,2-tetraflouroethane)- an environ-mentally compatible non-toxic non-flammable Freon substitute, BP = -26.2 °C; or

Chlorodiflouromethane (boiling point =-40 °C)

Further description:

Spraying an irradiated line for a duration 5ms so that the skin returns to its normal temperature within 10 to 20 ms will allow that portion of the skin to return to its normal temperature within the time interval it takes the scanned beam to complete it repositioning to the lower quadrant lateral scanning along the lower quadrant and returning to its original position for a adjacent scan of line 50.

Experimentally it can be shown that a burst of 5 ms reduces the temperature from about 30 ^{0}C to about 0 ^{0}C while recovery to about 20 ^{0}C occur within 10 to 20 ms.

The short time duration and small spot size allow energy to be removed both ablatively as well as through three-dimensional diffusion. However, if we follow up with a second line-scan close by, before heat had a chance to dissipate we slowly building up the effect of a large sot size and longer time duration. Further enhancement of cooling is achieved by cool/spray the targeted surface after a first line has been irradiated and before an adjacent line has been irradiated.

DISCLOSURE II

Small Spot Size With Low Energy Per Pulse

The Invention further discloses a method for utilizing very small per pulse energy sources. Such small pulse energy usually do not have enough fluence (energy per unit area) to ablate or modify a macroscopically significant area. However, in conjunction with scanners they can constitute a variable interaction source. Additionally, the very small size of the interaction spot size (5 - 250 μm) implies a very rapid spot cooling. Enhance by "spaced-scanning" such interaction can very significantly minimize thermal and mechanical impact.

WHAT IS CLAIMED:

1. A method for material removal and modification the method comprising the steps of:

generating a beam of a low energy, high pulse repetition rate, source of electromagnetic radiation, said high pulse repetition rate energy source has an average power of from about 0.0001 W to about 10 KW, and preferably from about 1mW to about 0.1KW. The pulses in the pulse train have a pulse duration from about 4 fs to about 100 ms and preferably from about 0.1 ps to about 1ms;

directing said beam at the material so as to ablate a quantity of the material and to permanently modify a quantity of the material, the beam is configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby and to enhance residual heat removal;

focusing the source's output beam to a small spot size in the range of from about 1µm to about 1mm and preferably in the range of from about 5 µm to about 0.2 mm);

generating a rapid beam movement;

generating a predetermined pattern of beam movement; and

using the means for generating the rapid beam movements to limit the dwell time (the time it takes the beam to sweep across a single point in space) so that a single pulse is delivered to each separate location in space before the beam moves on to the next location (i.e. there is no substantial spatial overlap of any two consecutive pulses delivered to the tissue).

2. The method of claim 1 further comprising means for moving the beam after a line segment is ablated or modified to ablate or modified a line segment substantially removed from said first line to be modified so that heat deposited in said first line is not sufficient to raise the temperature of the tissue in the vicinity of said second line above the threshold for significant volume of irreversible modification of the tissue, or the threshold for significant pain.

3. The method of claim 2 further comprising of the step of returning the beam after it has completed ablating or modifying the second line to the vicinity of the first line and ablating or modifying a third line, such ablation or modifying sequence is further continued as the beam is moved in alternating fashion between sequential lines below line 1 and line 2 until the entire pre-selected area is completely ablated or modified in a continuous and uniform manner.

4. The method of claim 1 further comprising the steps of cooling the ablated surface, said cooling of the ablated surface being applied after a line segment was ablated and before an adjacent line is ablated.

5. The method of claim 2 further comprising the step of cooling the ablated surface, said cooling of the ablated surface being applied after a line segment was ablated and before an adjacent line is ablated.

6. The method of claim 3 further comprising the step of cooling the ablated surface, said cooling the ablated surface being applied after a line segment was ablated and before an adjacent line is ablated.

7. The method of claim 1 further comprising the step of applying a coolant, which does not block or interfere with laser action, said coolant is applied after irradiation is completed.

8. The method of claim 1 further comprising applying a coolant prior to the irradiation step. However, this action must be made only as long as the coolant temperature reducing action is effective but the coolant itself does not block or interfere with the beam.

9. The method of claim 4 further comprising of the step of repeating the process to generate a second ablating or modifying pass over the entire designated area once interaction with first layer of material over the entire area has been completed.

10. The method of claim 1 further comprising utilizing a high pulse repetition rate (PRR) source whose average power is in the range of 0.1 mw to 1KW, whose pulse repetition rate is in the range of about 5.0 Hz to about 100 KHz and preferably in the range of from about 100 Hz to about 10 KHz, whose fluence is in the range of about 0.0001 J/cm^2 to about 500 J/cm^2 and preferably from about 0.01 J/cm^2 to about 50 J/cm^2; and its peak power is from about E4 W/cm^2 to about E 14 W/cm^2 and preferably from about

E8 W/cm^2 to about E10 W/cm^2; and its peak power density is from about E8W/cm^3 to about E 18 W/cm^3 and preferably from about E12W/cm^3 to about E14W/cm^3.

11. The method of claim 1 further comprising the use of an optical parametric oscillator or and optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

12. The method of claim 2 further comprising the use of an optical parametric oscillator or and optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

13. The method of claim 3, further comprising the use of an optical parametric oscillator or an optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly observed by the targeted material.

14. The method of claim 4, further comprising the use of an optical parametric oscillator or an optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

15. The method of claim 5, further comprising the use of an optical parametric oscillator or an optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

16. The method of claim 8, further comprising the use of an optical parametric oscillator or an optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

17. The method of claim 9, further comprising the use of an optical parametric oscillator or an optical parametric amplifier to shift said beam output wavelength to a wavelength which is strongly absorbed by the targeted material.

An exemplary device of the above would comprise:

A low power Microchip Laser of 1 kHz to 10 kHz pulse repetition rate with 100 mw pulse train, will yield (at, for example, 10 kHz)

100mw/10,000 pulses/sec = 10^{-2} mj/pulse =
10 microjoule/pulse

The energy per pulse is then: E/pulse = 10μJ/pulse with a spot size of 10μm

The resulting fluence per pulse of a microchip system is thus

Energy/ Pulse	Spot Size	Fluence Pulse
10 μJ/pulse,	10μm:	Fluence/Pulse = 10J/cm^2; P peak = 10E^{10} W/cm^2
10 μJ/pulse,	30μm:	Fluence/Pulse = 1J/cm^2 P peak = 10E^9 W/cm^2
10 μJ/pulse,	100μm:	Fluence/Pulse = 0.1J/cm^2 P peak = 10E^9 W/cm^2

At pulse duration of 1ns or less, its peak power is,

< 1ns: P peak = 10^{10} W/cm^2

A spot size somewhat larger than:

~30 μm, will results in a still reasonable fluence of

~30 μm: Fluence/Pulse ~ 1J/cm^2

A second example is a diode-pumped solid state laser (DPSS) which provide more energy per pulse. With an Optical parametric

Oscillator (OPO) a DPSS laser with a 15% conversion of a pulse energy of 10 mJ pulse.

Will yield 1.5 mJ over SS =10 μm yields ~1500 J/cm².

with a spot sized 30 μm; the Fluence/Pulse ~ 150 J/cm² P/Pulse = 1.5E10 W/cm²

With a spot sized 100 μm; the SS Fluence/Pulse = 15 J/cm² or P/Pulse = 1.5 E9 W/cm²

With a spot sized 300 μm; the SS Fluence/Pulse = 1.5 J/cm² or P/Pulse = 1.5 E8 W/cm²

Energy per Pulse (μJ)	Spot Size (μm)	Fluence Per Pulse (J/cm²)	Peak Power (W/cm²)
Microchip Laser			
10	10	10	1.0E10
10	30	1	1.0E9
10	100	0.1	1.0E9
Diode Pump Solid State DPSS			
10mJ out + OPO = 1.5 mJ	Spot Size (μm)	Fluence per Pulse (J/cm²)	Peak power per Pulse (W/cm²)
1.5 mJ	10	1500	1.5 E11
1.5 mJ	30	150	1.5 E20
1.5 mJ	100	15	1.5 E9
1.5 mJ	300	1.5	1.5 E8

A comparison of the microchip laser and the DPSS above shows that for the same spot size of 100um, the microchip laser has lower

Fluence by a factor of 150 but about the same peak Power. Thus the two are in the same plasma generating regime.

For comparison, a 4 mJ 1 μs pulse free-running micropulse of an Er:YAG (80 mJ/250 μs) with a 1mm spot, the fluence is only 0.4 J/cm^2. At 1μs its peak power is 4E5 W/cm^2

a 100mJ 200 µs pulse applied to 1 mm^2 yield a fluence of 10 J/cm^2 With P peak = 5 E4 W/cm^2

Where a particularly big advantage is obtained with these systems is with the High absorption at 2.9 μm WL)

We thus see that the peak power of the microchip laser is much like the free-running laser at 2.9 μm, even at 1mm spot sizes, while comparable fluences occur when the microchip laser spot size is ~ 0.1 mm.

A spot of 10 μm = E-3 cm --
(10 μm)^2 = E-6 cm^2
Thus at 1 KHz we have 1000 spots or a total area covered of 10E-3 cm^2/s = 0.1 mm^2 per second
At 10 KHz we have E4 spots/sec XE-6cm^2/spot =1mm^2/s

Of course, with the high absorption of water containing components, a considerably larger spot size can be used. For example, Water absorption at about 2.9 micrometer wavelength is 10^5 times larger than that of the 1.06 um (i.e, about 5 orders of magnitude larger). Consequently, a spot size 100 to 300 times larger can be used with 2.9 micrometer wavelength because the energy per unit volume will be the same as that of the smaller spot size (for example that of about 10 micrometer in size) 1.06 mm wavelength of radiation. Thus a spot size as large as 1 to 3 mm can be used even with the very low energy DPSS and microchip laser systems. In such cases very large areas can be removed or modified very rapidly.

CW AND SKIN PULSES REJUVENATING

WHAT IS CLAIMED IS:

1. A method for rejuvenating the skin, the method comprising the steps of:

directing a beam of electromagnetic energy at the material so as to ablate a small quantity of the skin, said quantity of the skin is substantially smaller than total thickness of the epidermis, the beam being configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby;

means for focusing the source's output beam to a small spot size (for example in the range of from about 1μm to about 2cm but preferably in the range of from about 10 μm to about 400 μm);

the continuous wave energy source having an average power of from about 0.001 W to about 10 KW, and preferably from about 1W to about 1KW; and

said beam of electromagnetic energy interacts with the same skin spatial location at a pulse repetition rate of from about 0.01 Hz and up to about 50 kHz and preferably at a rate of from about 0.3 Hz to about 30 kHz.

2. The method of claim 1, further comprising means for cooling the ablated surface, said means for cooling the ablated surface is applied to a point on the skin after said point on the skin has been ablated and before an adjacent point on the skin is ablated.

3. The method of claim 1, further comprising applying a coolant, which does not block or interfere with the beam action said coolant is applied after irradiation is completed.

4. The method of claim 1, further comprising applying a coolant prior to the irradiation step However, this action must be made only as long as the coolant temperature reducing action is effective but the coolant itself does not block or interfere with the beam.

5. A method for tissue processing, removal and modification while minimizing pain, the method comprising the steps of:

directing a beam of a continuous wave energy at the biological tissue so as to ablate a quantity of the material and/or to permanently modify a quantity of the material, the beam being configured to increase a ratio of the quantity of the material which is ablated thereby with respect to the quantity of the material which is permanently modified thereby, and minimizes pain; and

creating an ambient environment surrounding said ablated or modified tissue which minimizes chemical or physical stimulation to the ablated or modified target tissue.

In Summary:

First Note:

Claim 5 is important because it addresses the issue of pain, which is generated outside the actual interaction of and electromagnetic source or laser with the target tissue. Pain is generally generated form mechanical, chemical, or other physical stimulation of nerve ending. Thus when a region of animal tissue which contain nerve ending is exposed to for example pressure, air flow, heat, chemical reaction or any other type of physical and or chemical stimulation, pain is felt. Our method both minimizes the stimulation due to the actual action of the laser or electromagnetic source beam, and, as claim 5 above state, also address the issue of pain generated in the exposed tissue. By

creating an ambient environment (before, during or after beam action) which prevent temperature changes (and thus also, the associated mechanical changes) air flow, and in general any possible mechanical physical or chemical stimulation, much of the pain can be eliminated.

HAIR I

WHAT IS CLAIMED:

1. A method for removing hair from a region of skin, the method comprising the steps of:

coating the region of skin with a reflective material;

removing reflective material from a small (for example in the range of from about 1μm to about 3mm but preferably in the range of from about 10 μm to about 200 μm) area of skin proximate each hair to be removed; and

directing the source's output beam through said small area of the skin where the reflective coating has been removed and toward a papilla of each hair to be removed, the electromagnetic energy being configured to inhibit hair growth.

2. The method as recited in claim 1, further comprising the step of modifying the papilla and hair-sustaining tissue with the electromagnetic radiation.

3. The method as recited in claim 1, further comprising the step of destroying the papilla and hair sustaining tissue with the electromagnetic radiation.

4. The method of claim 1 further comprising generating rapid beam movement with, for example, motor-mounted mirrors.

5. The method of claim 4 further comprising generating a predetermined pattern of beam movement using, for example, electrical signal generator coupled to the motors which drive the mirrors.

6. The method of claim 5 further comprising of selecting interaction sites substantially separated from each other so that thermal energy diffusing from separate sites do not combine to raise target temperature above threshold temperature for irreversible damage.

7. The method of claim 5 further comprising applying a coolant to the target surface after irradiation to substantially and rapidly reduce target surface temperature after irradiation step.

7[1]. The method of claim 6 further comprising applying a coolant to the target surface after irradiation to substantially and rapidly reduce target surface temperature after irradiation step.

8. A method for removing hair from a region of skin, the method comprising the steps of:

directing the source's output beam through a small area of the skin toward a papilla of each hair to be removed, the electromagnetic energy being configured to inhibit hair growth; and

focusing the source's output beam to a small spot size (for example in the range of from about 1μm to about 5mm but preferably in the range of from about 10 μm to about 700 um).

9. The method as recited in Claim 8, further comprising the step of modifying the papilla and hair-sustaining tissue with the electromagnetic radiation.

10. The method as recited in Claim 8, further comprising the step of destroying the papilla and hair sustaining tissue with the electromagnetic radiation.

11. The method of claim 8 further comprising generating rapid beam movement, for example, using motor-mounted mirrors.

12. The method of claim 11 further comprising generating a predetermined pattern of beam movement.

13. The method of claim 12 further comprising of selecting interaction sites sufficiently removed from each other so that thermal energy diffusing from separate sites do not combine to raise target temperature other than hair-sustaining tissue, above threshold temperature for irreversible damage or significant pain.

14. The method of claim 13 further comprising applying a coolant to the target surface after irradiation to substantially and rapidly reduce target surface temperature after irradiation step.

15. The method of claim 13 further comprising applying a coolant to the target surface prior to irradiation to substantially and rapidly reduce target surface temperature after irradiation step, said coolant does not block or interfere with the beam interaction with the target tissue.

HAIR II:
WHAT IS CLAIMED:

1. A method for permanent hair removal comprising of:
obtaining a contrast map of the hair (i.e. contrasting the upper hair shaft color with the surrounding skin color). In

black hair on white skin this is natural, when black hair on black hair or white (or blonde) hair on white skin this can be accomplished by dying (i.e. coloring) the hair so it exhibits a high contrast color to the skin. This can also be accomplished by covering the skin with high reflective coating and then either shaving the hair shafts or pulling out the hair shafts;

obtaining a contrast map of hair locations and either:

directing a beam of electromagnetic energy of wavelength which is substantially not absorbed by the skin and is well absorbed by the hair pigments, the electromagnetic beam directed to each hair location is of a spot diameter large enough to ensure maximum deep penetration; or

directing an electromagnetic beam of wavelength which is substantially not absorbed by the hair shaft and is well absorbed by the blood vessels in the papilla, said electromagnetic beam is of a spot size optimized for maximum coupling to the hair shafts;

generating rapid beam movement;

said rapid beam movement thereby causes the beam dwell time (the time it takes the beam to move over a single point in space) to be limited from about 1 ps to about 1 second and preferably from 1μs to 100ms;

generating a predetermined pattern of beam movement; and

using the rapid beam movements to direct said beam to target sites on the skin surface containing hair shafts, whereby an exemplary site 3020 in Figure 3 is sufficiently removed from any other exemplary site 3040 so that the residual thermal energy from all irradiation at any given time is insufficient to cause irreversible damage to structures other than the hair follicle and is insufficient to cause a sensation of pain.

2. The method of claim 1 further comprising applying a substance to cool the irradiated sites said substance for cooling

the ablated sites is applied to each site after it is irradiated and before an adjacent site is irradiated.

3. The method of claim 1 further comprising applying a substance to cool the irradiated sites, said substance for cooling the ablated sites being applied to each site before it is irradiated.

The point is that the hair follicle need to be heated, not everything else. It is thus of very little significance at what order the heat is deposited. It is, therefore, possible to irradiated a predetermined area of a targeted hair-containing skin (e.g. 2cm X 2cm) with a predetermined pattern of "droplets" of electromagnetic radiation. For example a pattern of X irradiation sites in t seconds results in a total energy deposits of X * E/follicle = Etot/tsec such that said Etot of thermal energy deposited in a volume Vtot, Etot minus the energy diffused out of Vtot in t seconds is not sufficient to the raise said volume of target hair-containing skin to a temperature above the threshold temperature for pain. (i.e. if only 1 or 2 follicles are irradiated within an exemplary volume - not much heat is generated within the rest of the volume and within the complete heat dissipation time for the considered volume.

NEC/sfc

SFC IRV17322.1-*-12/8/98 12:21 pm

Docket No.	:	33826/NEC/Y54	CHRISTIE, PARKER & HALE, LLP Post Office Box 7068
Applicant or Patentee	:	Joseph NEEV	Pasadena, CA 91109-7068
Application or Patent No.	:		(626) 795-9900
Filed or Issued	:	Concurrently Herewith	
Entitled	:	A METHOD AND APPARATUS FOR SURGERY AND MATERIAL PROCESSING	

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR § 1.9(f) and § 1.27(b))
INDEPENDENT INVENTOR

As a below-named inventor, I declare that I qualify as an independent inventor as defined in 37 CFR § 1.9(c) for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled **A METHOD AND APPARATUS FOR SURGERY AND MATERIAL PROCESSING** described in

__X__ the specification filed herewith.

_____ Application No. __ filed __

_____ Patent No. __ issued __

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR § 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR § 1.9(d) or a nonprofit organization under 37 CFR § 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed, or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.

__X__ No such person, concern or organization.

_____ Persons, concerns or organizations listed below. (NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. 37 CFR § 1.27)

NAME :
ADDRESS :
___ INDIVIDUAL ___ SMALL BUSINESS CONCERN ___ NONPROFIT ORGANIZATION

NAME :
ADDRESS :
___ INDIVIDUAL ___ SMALL BUSINESS CONCERN ___ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR § 1.28(b))

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR § 1.9(f) and § 1.27(b))
INDEPENDENT INVENTOR

Docket No.: 33826/NEC/Y54

knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Joseph Neev	Joseph Neev	12/7/98
Name of Inventor	Signature	Date
Name of Inventor	Signature	Date
Name of Inventor	Signature	Date
Name of Inventor	Signature	Date

NEC/sfc

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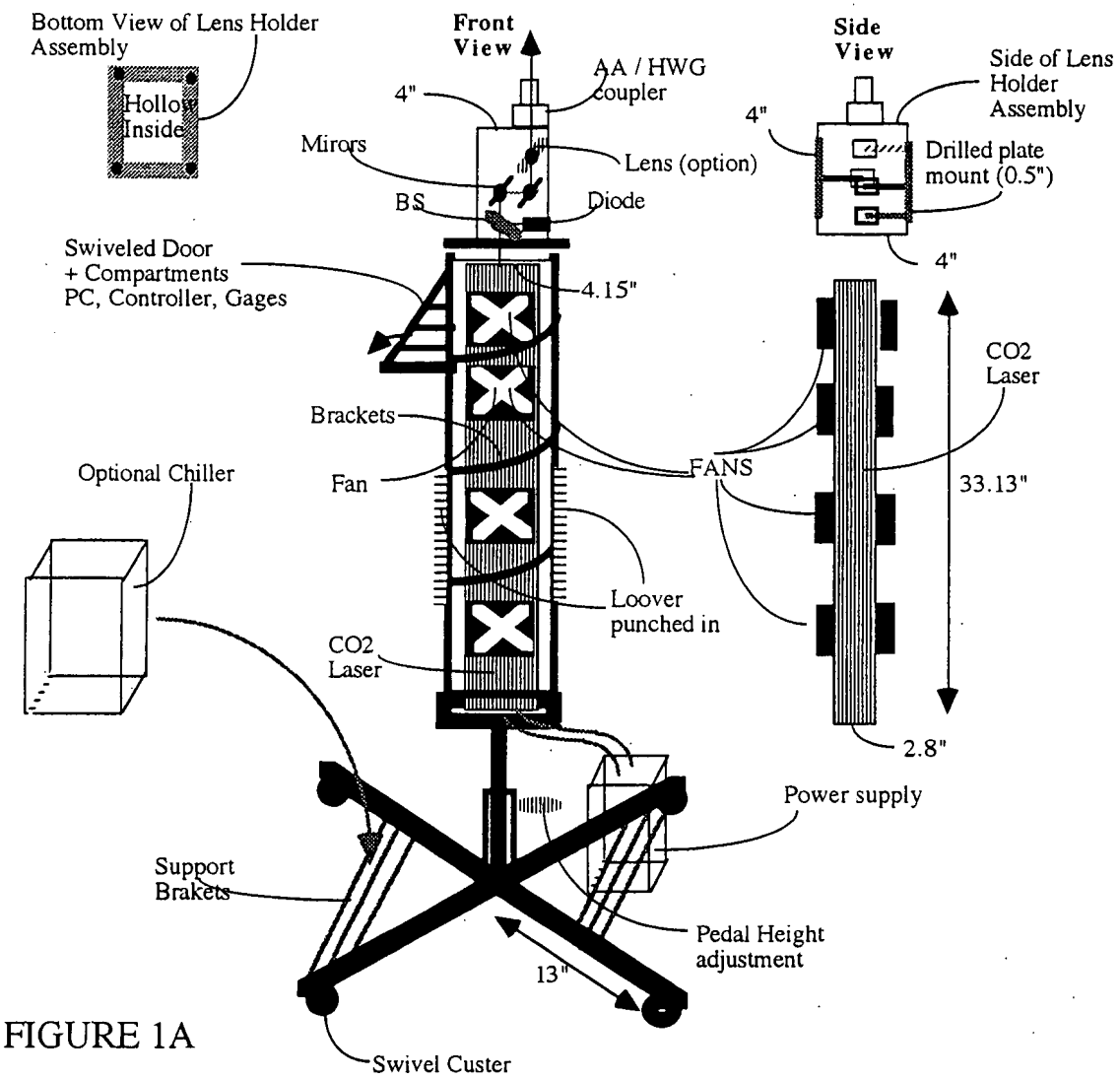


FIGURE 1A

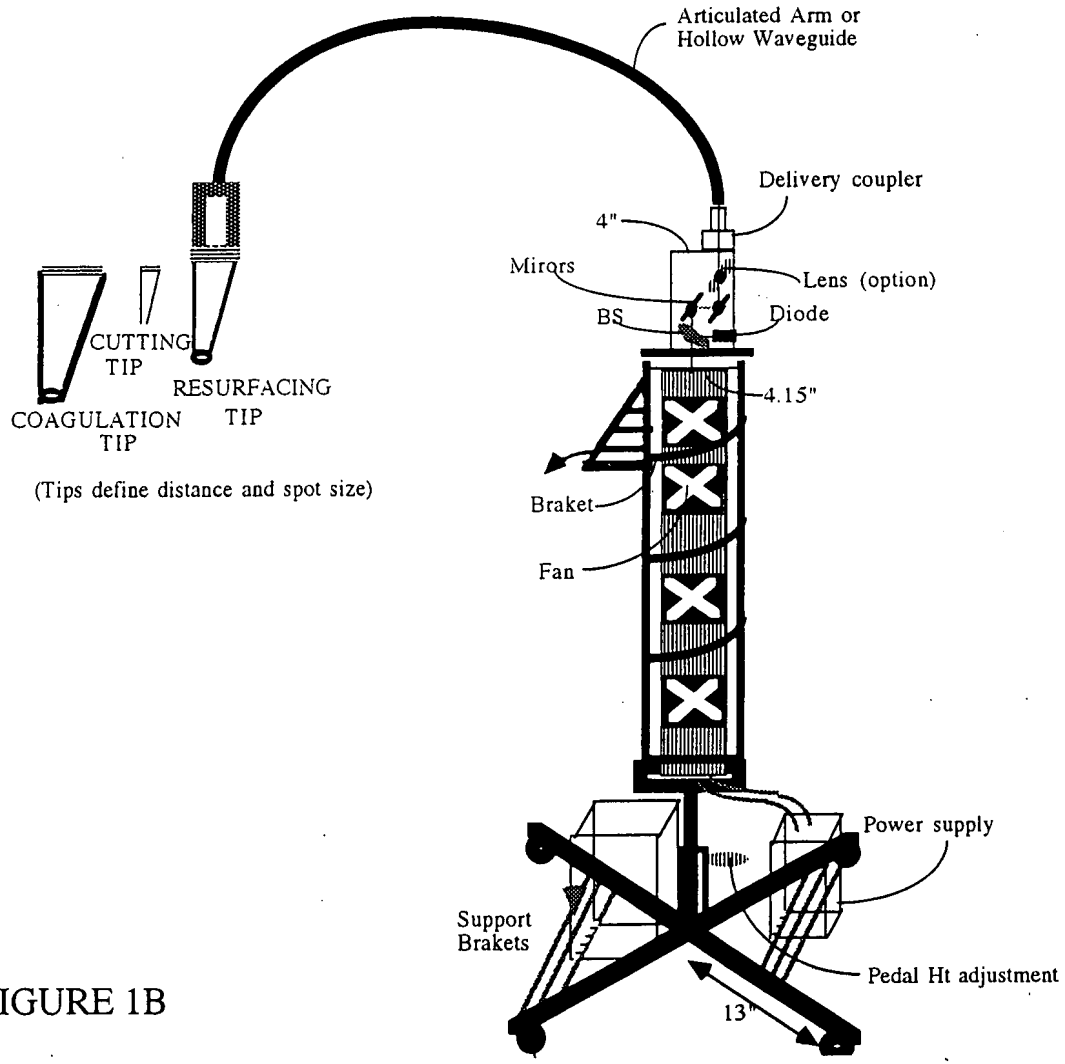


FIGURE 1B

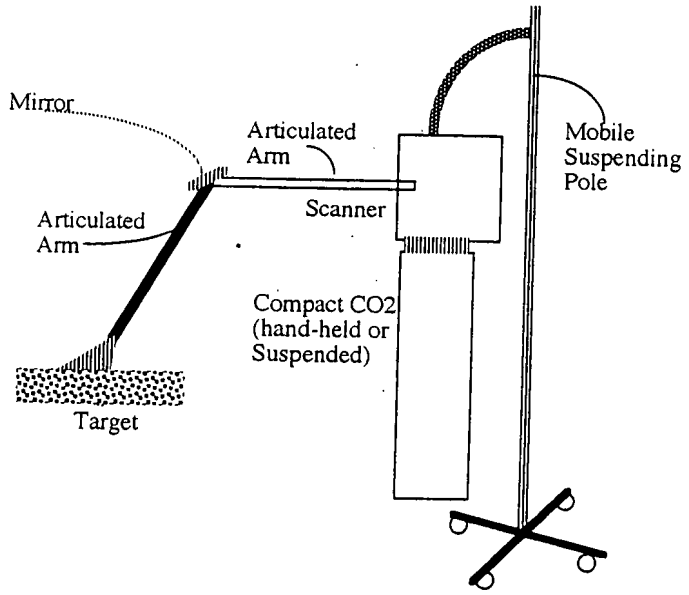


FIGURE 1C

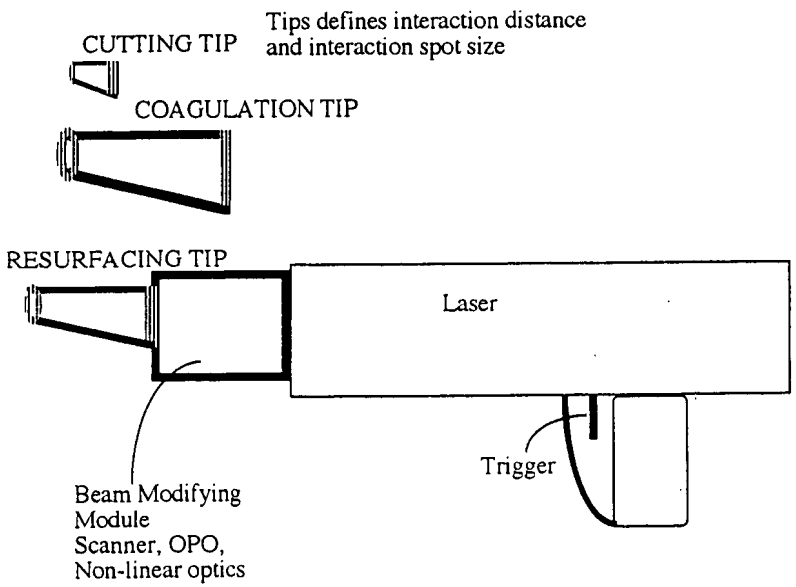
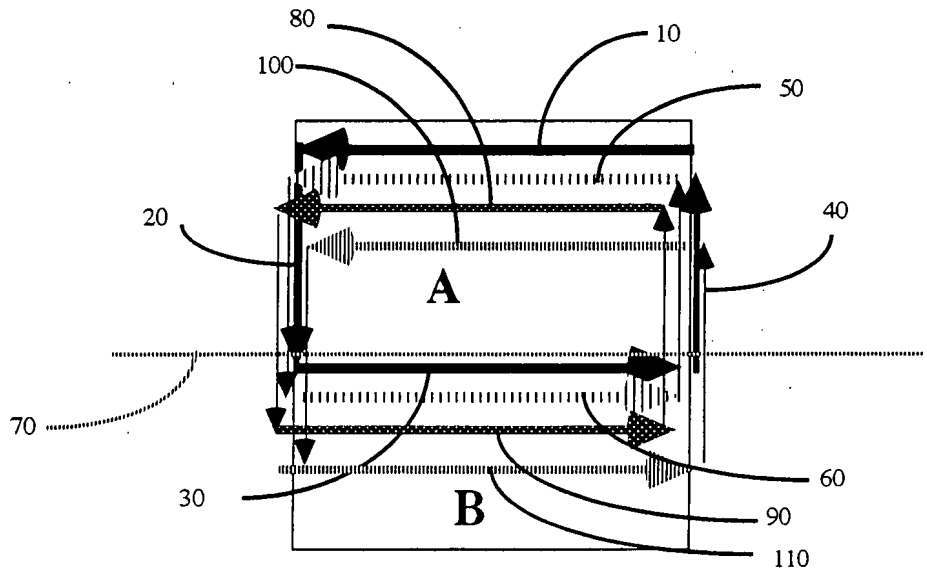
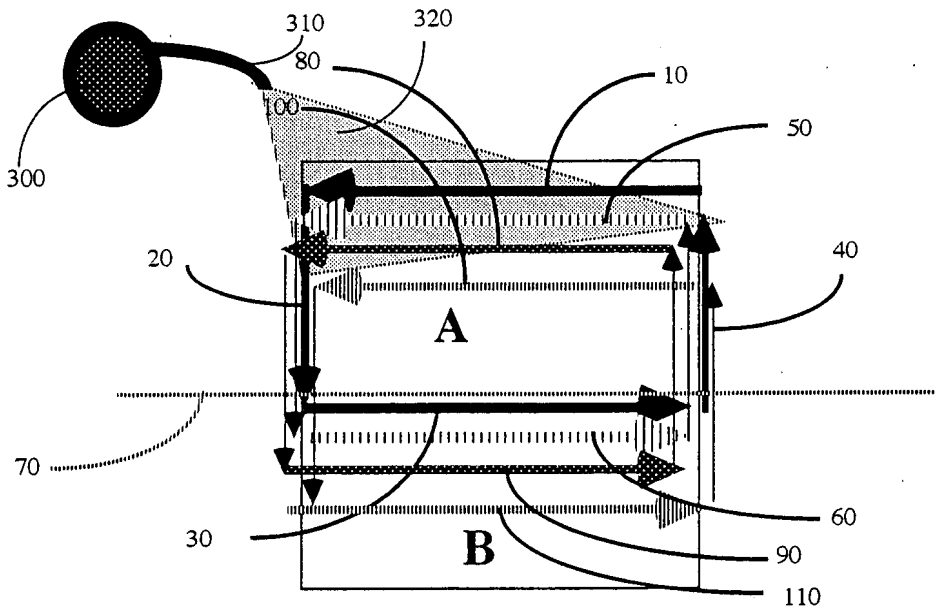


FIGURE 1D



Vertical Lines represent paths along which Laser is Off
Horizontal Line represent paths along which Laser is On
(4 paths shown)

FIGURE 2A



Vertical Lines represent paths along which Laser is Off
Horizontal Line represent paths along which Laser is On
(4 paths shown)

FIGURE 2B

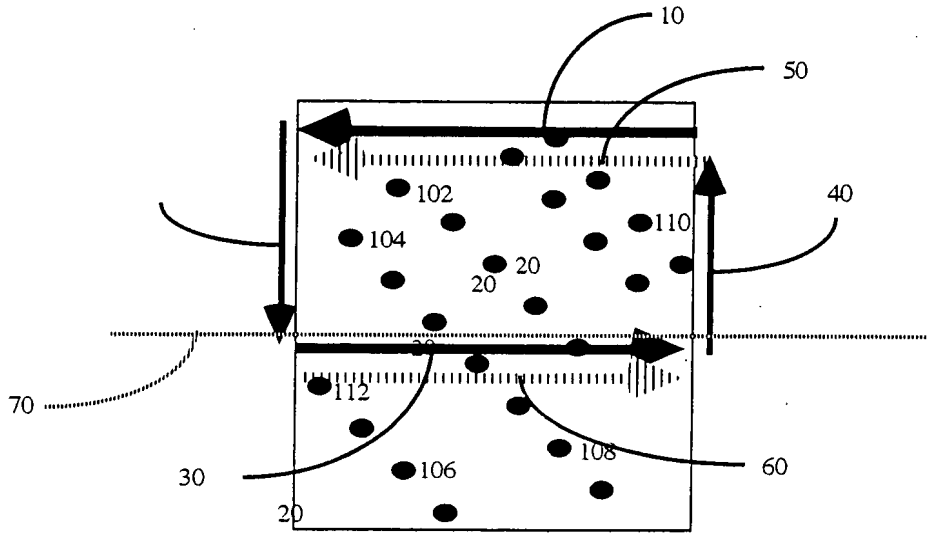


FIGURE 3

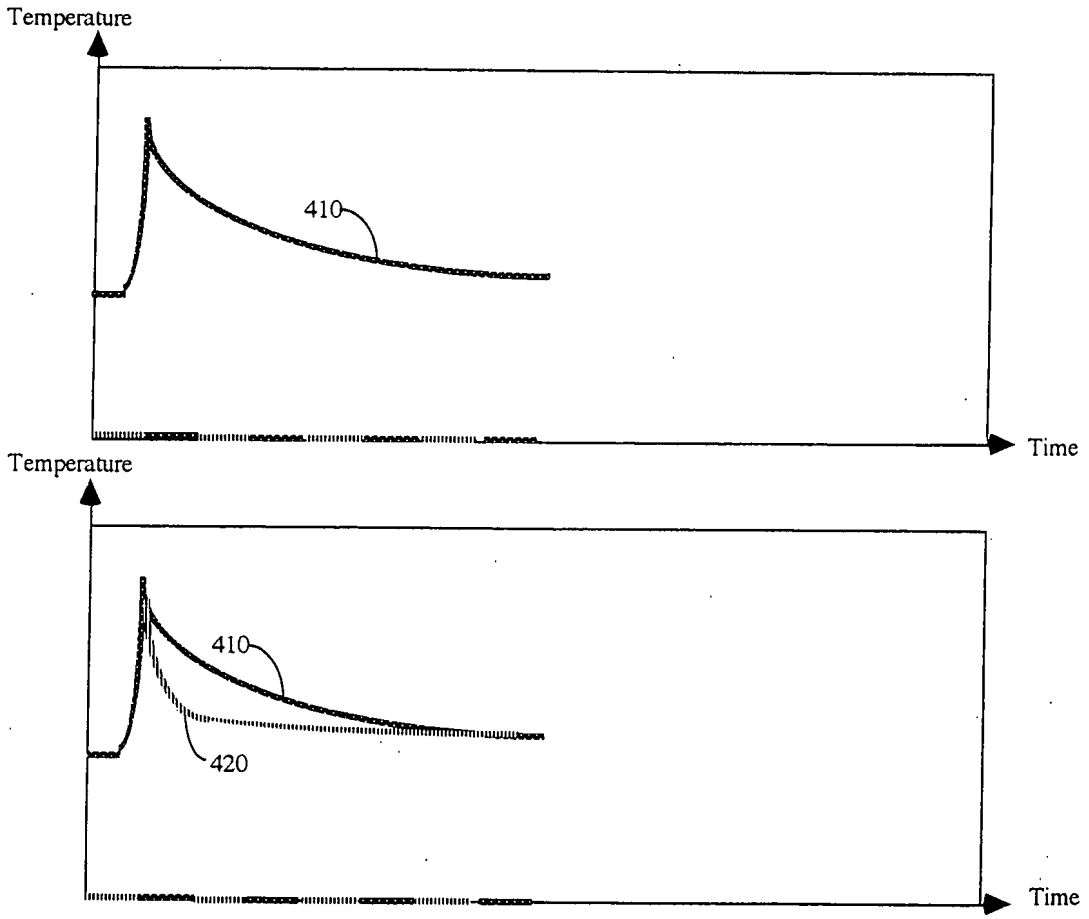


FIGURE 4A

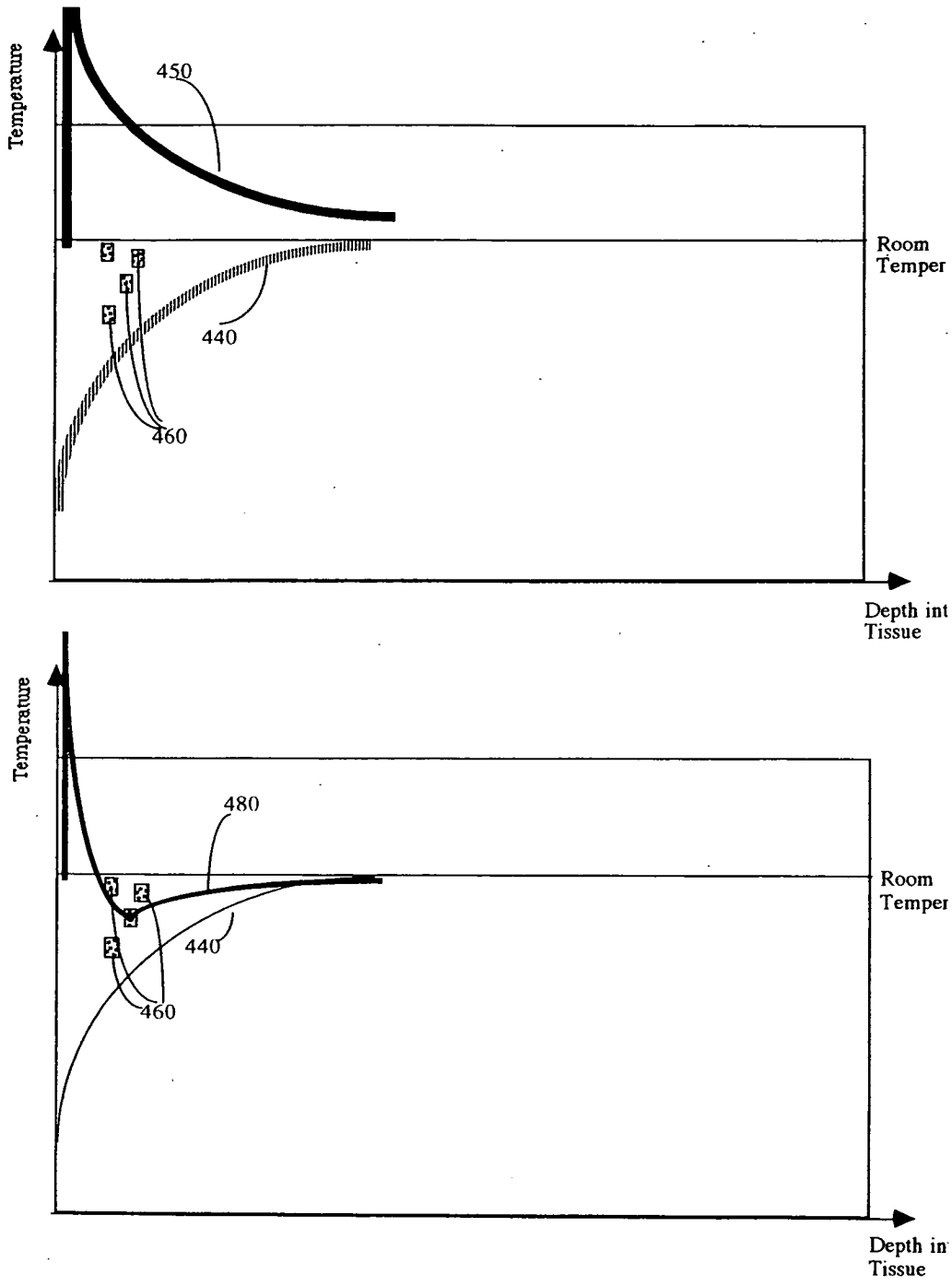

Temperature
450
Room Temper
440
460
Depth int Tissue
Temperature
480
Room Temper
440
460
Depth in Tissue

FIGURE 4B

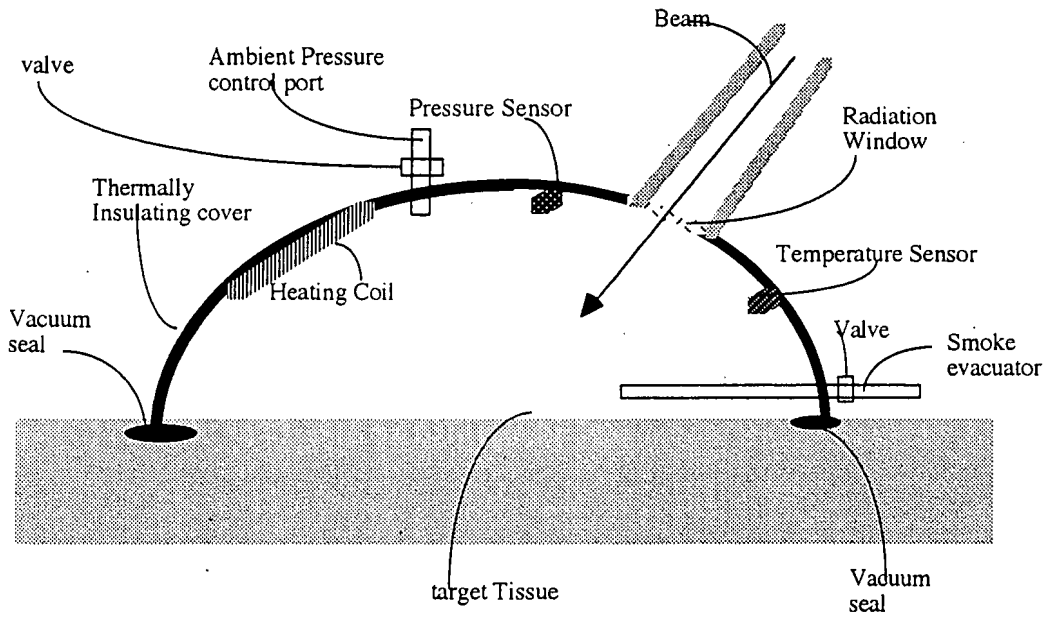


FIGURE 5

contain greater amounts of a light absorbing chromophore, for example, the carotenoid β-carotene, relative to lesser or non-pigmented surrounding cells. In the chromophore based methods it can be difficult to get sufficient chromophore in the target region to elicit selective tissue damage and the method may still damage the outer layers of the skin resulting in scarring.

Summary of the Invention

The present invention addresses the foregoing problems and provides a method for treating sebaceous follicle disorders of mammalian skin, for example, human skin. The method permits treatment of the sebaceous follicle disorder while at the same time preserving surrounding skin tissue, for example, skin epidermis. The invention offers numerous advantages over existing treatment protocols. For example, the method provides a long lasting treatment which persists long after treatment has ceased. Furthermore, the method minimizes trauma and scar formation at the skin surface, reduces side-effects, such as, pain, erythema, edema, and blistering, which can result from other treatments, and can also minimize pigmentary disturbances of the skin.

In one aspect, the present invention features a method of treating a sebaceous follicle disorder in a preselected region of mammalian skin, the preselected region having at least one lesion characteristic of the disorder disposed therein. The method comprises the steps of (a) cooling an exposed surface of the preselected region of the mammalian skin and (b) applying heating energy to the preselected region in an amount sufficient to ameliorate the lesion disposed within the preselected region. Without wishing to be bound by theory, it is contemplated that amelioration of the lesion can result from the destruction of the sebaceous follicle, structural changes to the sebaceous follicle to reduce the possibility of pore blockage, and/or reduction of sebum production by the sebaceous gland associated with the sebaceous follicle. As will be discussed in more detail below, the cooling step can be performed prior to and/or contemporaneous with the step of

applying the heating energy. Furthermore, it is contemplated that the cooling step can be performed after the heating step.

In a preferred embodiment, the heating energy is provided by means of a beam of radiation (for example, coherent or incoherent radiation), microwaves, ultrasound or radio frequency (RF) current. More preferably, the heat energy originates from a source of radiation, and most preferably from a source of coherent radiation. The source of the coherent radiation can be, for example, a pulsed, scanned, or gated continuous wave (CW) laser.

In a preferred embodiment, the beam of radiation comprises a wavelength in the range from about 0.6 microns to about 1.8 microns, more preferably in the range from about 1.2 to about 1.6 microns, and more preferably in the range from about 1.3 to about 1.6 microns. Most preferably, the beam has a nominal wavelength of about 1.5 microns. The beam preferably has either a fluence in the range from about 5 to about 500 joules per square centimeter, and more preferably in the range from about 10 to about 150 joules per square centimeter, or a power density in the range of about 1 to about 10,000 watts per square centimeter, and more preferably in the range from about 5 to about 5,000 watts per square centimeter.

During practice of the invention, application of the heating energy can induce thermal changes to the portion of the dermis where sebaceous follicles reside. This heating may result in the destruction of the sebaceous follicle or the sebaceous gland associated with the follicle, cause structural changes in the follicle to reduce the likelihood of blockage and/or reduce the level of sebum production. The cooling step serves to preserve the epidermis and the dermis overlaying the sebaceous gland containing region of the skin thereby reducing side-effects such as pain, erythema, edema, and blistering which otherwise may result from exposure to the beam of radiation. The cooling step can be performed prior to, contemporaneous with, or after application of the energy to the target region, or alternatively the cooling can result from a combination of such cooling steps.

Cooling can be achieved using many different techniques known and used in the art. For example, cooling can be achieved by blowing a stream of cold air or gas onto the target site, by applying a cold liquid onto the target site, by conductive cooling using a cold contact surface applied to the target site, or by evaporative cooling using a low boiling point liquid applied to the target tissue. In a preferred embodiment, cooling is achieved using evaporative cooling technologies by means of, for example, a commercially available dynamic cooling device (DCD).

Practice of the invention can be prophylactic or can be performed to ameliorate one or more symptoms or lesions associated with the various sebaceous follicle disorders. Exemplary sebaceous follicle disorders include, for example, acne, for example, acne vulgaris, acne rosacea, and acne conglobata, seborrhea, sebaceous adenoma and sebaceous gland hyperplasia. The present invention, however, is particularly useful in the treatment of acne, more specifically, the treatment of acne vulgaris.

Sebaceous follicle disorders, for example, acne vulgaris and seborrhea, sometimes are associated with the overproduction of sebum. For example, in acne vulgaris, the level of sebum production by sebaceous glands has been correlated with the severity of the disorder (Leyden (1995) J. AM. ACAD. DERM. 32: S15-25). Accordingly, in a preferred embodiment, the method of the invention lowers or even eliminates sebum production by sebaceous glands of sebaceous follicles relative to untreated sebaceous follicles. In another embodiment, treatment can increase the size of the opening of the sebaceous follicle, in the proximity of the infundibulum, thereby affecting sebum flow and/or minimizing the likelihood of blockage of the sebaceous follicle. Furthermore, treatment may destroy or inactivate the sebaceous follicle thereby eliminating sebum production in that follicle.

Application of the heating energy can reduce the size of one or more lesions, for example, comedones in the case of acne vulgaris, disposed within the preselected region. Furthermore, application of the heating energy can also reduce the density of the lesions disposed within the preselected region. In cases in which skin inflammation can be

associated with the lesion, for example, in severe cases of acne vulgaris and acne conglobata, the application of the heating energy may reduce the inflammation associated with the lesion. The benefit of treatment, for example, reduction in the number of or elimination of skin lesions, may become apparent days to weeks after the treatment. Furthermore, it is contemplated that in certain cases, e.g., severe cases, of sebaceous follicle disorders, multiple rounds of treatment, for example, two to ten separate rounds of treatment, may be required to treat an individual satisfactorily.

It is contemplated that, based upon choice of appropriate cooling and/or heat energy parameters, it is possible to create thermally induced changes of sebaceous follicles in the absence of an exogenous energy absorbing material. However, under some circumstances, for example, when heating is accomplished by the application of a radiation beam, optimal treatment may be facilitated by applying to the preselected region prior to exposure to the radiation beam a radiation absorbing material, for example, a chromophore photoexcited by the radiation. The radiation absorbing material may be administered systemically to the mammal or applied topically to the preselected region prior to exposure to the radiation beam.

Exhibit B

What is claimed is:

1. A method of treating a sebaceous follicle disorder in a preselected region of mammalian skin, the preselected region having at least one lesion characteristic of the disorder disposed therein, the method comprising the steps of:

(a) cooling an exposed surface of the preselected region; and

(b) applying energy to the preselected region in an amount sufficient to ameliorate the lesion.

2. The method of claim 1, wherein in step (b) the energy is provided by laser light, incoherent light, microwaves, ultrasound or RF current.

3. The method of claim 1 wherein in step (b) the energy is provided by laser light.

4. The method of claim 3, wherein the laser light comprises a wavelength in the range from about 0.6 microns to about 1.8 microns.

5. The method of claim 4, wherein the wavelength is in the range from about 1.2 to about 1.7 microns.

6. The method of claim 5, wherein the wavelength is in the range from about 1.3 to about 1.6 microns.

7. The method of claim 6, wherein the wavelength is about 1.5 microns.

8. The method of claim 3, wherein the laser light comprises a fluence in the range from about 5 to about 500 joules per square centimeter.

9. The method of claim 7, wherein the fluence is in the range from about 10 to about 150 joules per square centimeter.

10. The method of claim 1, wherein the laser light comprises a power density in the range from about 1 to about 10,000 watts per square centimeter.

11. The method of claim 1, wherein step (a) occurs prior to step (b).

12. The method of claim 1 or 11, wherein step (a) occurs contemporaneously with step (b).

13. The method of claim 1, comprising the additional step of prior to step (b) providing a radiation absorbing material to the preselected region.

14. The method of claim 1, wherein in step (b) the thermal change occurs in the absence of an exogenously provided radiation absorbing material.

15. The method of claim 1, wherein the disorder is acne.

16. The method of claim 15, wherein the acne is acne vulgaris.

17. The method of claim 1 or 15, wherein applying energy in step (b) reduces the size of a lesion disposed within the preselected region.

18. The method of claim 1 or 15, wherein applying energy in step (b) reduces the density of lesions disposed within the preselected region.

19. The method of claim 1 or 15, wherein applying energy in step (b) reduces lesion-associated skin inflammation in the preselected region.

20. A method of treating acne in a preselected region of mammalian skin, the preselected region having at least one acne lesion disposed therein, the method comprising the steps of:

(a) cooling an exposed surface of the preselected region; and

(b) exposing the preselected region to a beam of radiation comprising a wavelength in the range from about 0.6 microns to about 1.8 microns to ameliorate the lesion.

21. The method of claim 17, wherein in step (b) the wavelength is in the range from about 1.2 to about 1.7 microns.

22. The method of claim 21, wherein the wavelength is in the range from about 1.3 to about 1.6 microns.

23. The method of claim 22, wherein the wavelength is about 1.5 microns.

24. The method of claim 20, wherein in step (b) the beam of radiation has a fluence in the range from about 5 to about 500 joules per square centimeter.

25. The method of claim 24, wherein the fluence is in the range from about 10 to about 150 joules per square centimeter.

26. The method of claim 20, wherein in step (b) the beam of radiation has a power density in the range from about 1 to about 10,000 watts per square centimeter.

27. The method of claim 26, wherein the power density is in the range from about 5 to about 5,000 watts per square centimeter.

28. The method of claim 20, wherein step (a) occurs prior to step (b).

29. The method of claim 20 or 28, wherein step (a) occurs contemporaneously with step (b).

30. The method of claim 20, comprising the additional step of prior to step (b) providing a radiation absorbing material to the preselected region.

31. The method of claim 20, wherein the disorder is acne vulgaris.

32. The method of claim 20, wherein applying energy in step (b) reduces the size of a lesion disposed within the preselected region.

33. The method of claim 20 or 32, wherein applying energy in step (b) reduces the density of lesions disposed within the preselected region.

34. The method of claim 20, 32 or 33, wherein applying energy in step (b) reduces lesion-associated skin-inflammation in the preselected region.